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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
IZAGUIRRE, ISMAEL	
ART UNIT	**PAPER NUMBER**
3765	

DATE MAILED: 11/07/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/846,876	SAADAT, VAHID	
	Examiner	Art Unit	
	Ismael Izaguirre	3765	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,26,31-49,52-54,56 and 57* is/are rejected.

7)☒ Claim(s) *23-25,27-30,50,51 and 55* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The examiner is appreciative of the changes made to the specification and the language of the claims. These have been duly noted and considered.

CLAIMS

Summary

Claims 1 and 38 are the independent claims under consideration in this Office action.

Claims 2-37 and 39-57 are the dependent claims under consideration in this Office action.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,4,6-9,11,13-16,19,21,22 and 33 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gianturco (5,334,210).

Gianturco teaches an embolizing device for insertion into an aneurysm. Gianturco teaches a least one detachable self-expanding member 18 configured to be sealed within a membrane 11. The membrane defining a volume and further defining at least one orifice 19 in a surface of the membrane.

The self-expanding member 18 comprises an elongated flexible member, which includes a first configuration (much like the single wire embodiment noted in applicant's specification, paragraph 59) conforming to the internal shape of a positioning catheter 12 having a tubular cross-section. In the first configuration, the member, which is made up of a tungsten/platinum alloy wire, is fed to the site intended through the tubular internal cavity of the catheter. In the second configuration the wire member 18 expands (much like applicant's embodiment, paragraph 59) and is convoluted so as to fill the membrane at the aneurysm site. The member includes a distal end with a J-curve portion and enlarged end segment 25. This preformed hook-shaped portion is at first fed through the internal cavity as an unbent straight portion and when exiting the cavity, the J-curved portion expands or bends (column 4, line 35) or facilitates the bending of the member into a convoluted configuration for filling and expanding the bag at the aneurysm. This bending of the J-curve as it exits the catheter accomplishes or at the very least aids in the self-expanding function of the member.

Re claims 2, and 13-15, the member 18 is taught as attached to a joint 27,34 and 14 and is detachable from this joint. When the member is expanded the member is released from the joint.

Re claim 4, the member 18 is taught as being formed of a tungsten/platinum alloy and includes a J-shaped distal portion taught as expanding or bending into a J-shape, accordingly, the member comprises a shape memory alloy.

Re claim 6, the J-shaped portion of member 18 is taught as being fed through a catheter in a first unbent configuration. This would require the J-shaped portion to be

compressed into a catheter conforming shape before it exits the catheter and thus is compressed into a first configuration and then expands at the exit to form the J-shape defined by Gianturco.

Re claims 7-9, the member is taught as having a coil shape (see figure 3, for example). Bending and convoluting the member into a membrane-filling configuration will form a coil or coils of greater diameter. The member itself includes coiled wire with circular cross-sectional areas.

Re claim 11, pushing the member through the catheter stimulates the member and this pushing/stimulation causes the member to convolute and fill the membrane in the second configuration.

Re claim 19, the membrane is taught as having an opening and is connected to the end of the catheter, which is in fluid communication all along and to the proximate end of the catheter. Accordingly, the membrane is in fluid communication with the proximal end of the catheter.

Re claims 21 and 22, the bag is taught as expandable (see column 1, line 46, for example) and taught as made of nylon (column 2, line 1), which is biocompatible.

Remarks

Applicant argues that Gianturco '210 is not applicable since it does not teach at least one self-expanding member. The examiner does not agree. The member of Gianturco is taught as having a J-shaped portion 28 (figure 2). This is a preformed structural element of the member. When this J-shaped portion is fed through the catheter it assumes a "straightened" compressed configuration, and when it exits the

catheter the portion "pops" /expands or bends to this preformed J-shaped configuration. This is not a result of the pushing of the member through the catheter but a "memory" of a preformed shape it has. This anticipates the self-expanding limitation of the independent claim. This J-shaped portion further helps in directing the rest of the member to bend and convolute for filling the volume of the bag. Further, the wire itself is coiled into a spiral along its entire length and when this exits the catheter, the wire is bent or "curved" into large convoluted coils and not "fold-over" itself, like saying for example, a flat sheet of licorice. The end result is a self-expanding convoluted coil structure.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Remarks

Van Der Burg is a document submitted with the Information Disclosure Statement of paper # 8. This document is considered pertinent. The following is submitted for applicant's consideration:

Claims 1,2,4-9,11,13-16,19,21,22,26,33 and 34 are rejected under 35 U.S.C. § 102(e) as being anticipated by Van Der Burg et al (WO 00/27292).

Van Der Burg et al teach an embolizing device for insertion into an aneurysm. Van Der Burg et al teach a least one detachable self-expanding member 60 (see figures 6-8) configured to be sealed within a membrane 72. The member is defined as self-expanding (page 7, line 16) and, for example, including a structure of struts and linked elements attachable to the end of a delivery catheter. The membrane is defined as acting as a shield between the self-expanding member 65 and the inner surface of a patient's body cavity. The sheath is defined (see page 7, lines 25-33) as having a volume and covering all or part of the member (thus including an opening if partly covering the member).

The self-expanding member 60 comprises a structure such that it includes a first configuration conforming to the internal shape of a positioning catheter (figure 9) having a tubular cross-section. In the first configuration, the member including the sheath/membrane is fed to the site intended through the tubular internal cavity of the catheter. In the second configuration the wire member 60 self expands and fills the membrane at the aneurysm site.

Re claims 2, and 13-15, the member 60 is taught as attached to a joint 73 and is detachable from this joint. When the member is expanded the member is released from the joint.

Re claims 4 and 5, Van Der Burg et al teach that the expandable members of the embodiments of the invention, such as 60, are taught as being formed of a pseudo elastic/memory alloy NiTi alloy or a high strength material (see page 6, lines 18-31) such as stainless steel.

Re claims 6-9, the self-expanding member 60 is taught as being fed through a catheter in a first compressed configuration and then expanded in a second configuration. The physical structure of the member 60 is taught as comprising a coil 125 (figure 15), a first diameter and then a second diameter (compressed and then expanded) and having a cross-sectional shape including star shaped links (figure 8).

Re claims 11,13-16 and 19, the member 60 is taught as including a hub 72 and this is connected to the guiding member or catheter for placement at the desired site. The catheter would be in fluid communication from a distal end to the proximal end. The member is taught as stimulated by pushing the member through the catheter or stimulated by another form of energy (page 7, line 15-77) such as an electrical energy which, when applied, would erode the connection between the member and the connection.

Re claims 21 and 22, the bag is taught as expandable/distensible and formed of a biocompatible material (page 7, line 30).

Re claims 26,33 and 34, Van Der Burg teaches attaching the expandable member to an outer sheath or balloon (see page 7, lines 18-24).

Remarks

Greenhalgh is a newly found prior art document. The following is submitted for applicant's consideration:

Claims 1-22,31-33,35-49,52-54,56 and 57 are rejected under 35 U.S.C. § 102(e) as being anticipated by Greenhalgh (6,346,117).

Greenhalgh teaches an embolizing device for insertion into an aneurysm. Greenhalgh teaches a least one detachable self-expanding member 78 (see figure 11) configured to be sealed within a membrane 42. The member is defined as self-expanding (column 8, line 39) and includes a self-expanding wire structure in the form of a coil. The membrane is defined as an expandable bag having a volume including an opening (column 7, lines 46-47).

The self-expanding member 78 comprises a structure such that it includes a first configuration conforming to the internal shape of a positioning catheter 26 having a tubular cross-section. In the first configuration, the member including the membrane is fed to the site intended through the tubular internal cavity of the catheter (see figure 5, for example). In the second configuration the wire member 78 self-expands and fills the membrane at the aneurysm site.

Re claims 2, and 13-15, the coil 78 is taught as attached to a feeding wire and "snaked" up the catheter. When the self-expanding member is in place, the wire is released (column 9, line 34).

Re claim 4, Greenhalgh teaches that the expandable member 78 is formed of a great resiliency, high yield stress material and biocompatible.

Re claims 3,5,39,42 and 57, Greenhalgh teaches a stent or expanding member 78 and further teaches NiTi fibers or yarns enclosed or forming part of the bag 42. These NiTi elements are self-expanding for aiding the bag to expand. These constitute the second of the at least two members.

Re claims 6-8,33,40,43,53 and 54, the self-expanding member 78 is taught as being fed through a catheter in a first compressed configuration and then expanded in a second configuration. The physical structure of the member is taught as comprising a coil, a first diameter and then a second diameter (compressed and then expanded), which would touch the inner surface of the membrane. The cross-section of the member would include a circular shape. The final expanded shape would include a spherical shape.

Re claims 11-20,44,45 and 52, pushing the member through the catheter stimulates the member. The member 78 is taught as including a connection and is taught that it is released by mechanical or electrical current means (see column 2, lines 5-25). In the case of the electrical release, a current is passed through the catheter and erodes the connection point at the stent 78.

Re claims 21 and 22, the bag is taught as distensible and biocompatible (column 3, lines 31-38).

Re claims 31 and 32, the bag of Greenhalgh is taught as being formed of 5 to 100 denier and this anticipates these claims.

Re claims 35 and 36, the bag has an orifice of .005 inches, which would accommodate the wire to passing therethrough, which is taught as having a diameter of .005 inches (column 1, line 42).

Re claim 37, Greenhalgh teaches the bag including at least one main opening and being further porous for allowing blood to enter or aspirate into the bag and promote clotting. See column 6, line 65 and column 3, line 3.

Re claim 38, and 46-49, Greenhalgh teaches increasing a volume of a distensible member or bag 42 having at least one opening. Greenhalgh teaches the bag being porous (column 6, line 46) and allowing blood to aspirate (column 3, line 1) therethrough and aid in the clotting of the blood within the bag by electrothrombosis (column 9, lines 22-40). A self-expanding member is placed inside the bag and the bag itself is further provided with NiTi elements.

ALLOWABLE SUBJECT MATTER

Claims 23-25,27-30,50,51 and 55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

PERTINENT CITATIONS

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Forber illustrates an occlusion device including a self-expanding member with a film thereover.

INQUIRIES

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0861.

Any inquiry concerning this communication or earlier communications directed to the examiner should be directed to Mr. Ismael Izaguirre at (703) 308-0892 located in CP2-4B18, Monday through Friday 9:30am to 6:00pm.

Ismael Izaguirre
Primary Examiner
Group Art Unit 3765

II
11/5/03